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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/284,424 04/09/99 ALBRECHT H 5500-01-TMC

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HM22/0222

EXAMINER

MAIER, L.

ART UNIT

PAPER NUMBER

1623

12

DATE MAILED:

02/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/284,424

Applicant(s)

Albrecht et al

Examiner

Leigh Maler

Group Art Unit

1623



☒ Responsive to communication(s) filed on amendment filed December 6, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-8, 10-30, 34, 38-41, and 44-51 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8, 10-30, 34, 38-41, and 44-51 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Status of the Claims

Claims 1 and 20 have been amended. Claim 31 has been canceled. Claim 51 has been added. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any rejection or objection not expressly repeated has been withdrawn.

Claim Rejections - 35 U.S.C. § 112

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed December 6, 2000 have been fully considered but they are not persuasive. Applicants contend that *ipsis verbis* disclosure is not necessary to satisfy the written description requirement. The examiner agrees. However, the applicants have not pointed out where in the specification there is support, explicit or implicit, for each and every limitation in the amendment.

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Claim Rejections - 35 U.S.C. § 103

Claims 1-8, 10-30, 34, 38-41, and 44-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prasad et al (Bioorg. & Med. Chem. Lett., 1995) in view of Mjalli et al (Bioorg. & Med. Chem. Lett., 1994), Dolle et al (EP 0623592), and Chapman (US 5,430,128).

Applicants' arguments filed December 6, 2000 have been fully considered but they are not persuasive. Applicants argue that the examiner has not made an adequate showing on the record of the three required elements of a *prima facie* case of obviousness.

Suggestion or motivation to combine references: As discussed in paper no. 8, Prasad teaches the structural requirements for rational design of ICE inhibitors in which the most potent ones are aspartate α -(arylacyl)oxymethyl ketones with zero (only a protecting group) to three (natural/unnatural, protected/non-protected) amino acids attached through the aspartate amine moiety--that is, variable R¹ in the instant formula I. This art-disclosed common core plus common utility would give the artisan sufficient suggestion and motivation to combine the recited references.

Reasonable expectation of success: Although there is no perfect predictability in drug design, all of these references teach potent ICE inhibitors with the same compound core, as discussed above, with a variety of modifications on either end, corresponding to R¹ and R² in formula I. Based on the overlapping sets of compounds and teachings with regard to desired structural elements, one of ordinary skill in the relevant art would have a reasonable expectation of success.

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All limitations must be taught: Applicants assert that "...the rejected claims encompass compounds comprising substituents at the R¹ position. . .that are not taught by any of the art cited. . ." As discussed above, the art teaches zero to three amino acids in this position. The compounds with zero amino acids have only a common amino acid protecting group. See, for example, Prasad - compounds 4 and 9. In the absence of unexpected results, the substitution at this position with any common amino acid protecting groups would be an obvious variation.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Note: The claims still have reference to non-elected subject matter. Applicants are reminded of the election of non-heterocyclic compounds affirmed in paper no. 7.

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Examiner's hours, phone & fax numbers and other useful information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Monday-Friday 7:30 to 4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist (703) 308-1701, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Secure and confidential access to patent application status is now available; see <http://www.uspto.gov/ebc/index.html> for more information.

Applicant(s) may pay patent maintenance fees, non-filing application fees and maintain USPTO accounts through <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm>

Leigh C. Maier
Patent Examiner
February 20, 2001



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